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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/187,879	01/27/94	ROBINSON	H	UMMC9103A2

HM22/0530

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EXAMINER	
CLARK, D	
ART UNIT	**PAPER NUMBER**
1633	39

DATE MAILED: 05/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/187,879	Robinson et al.
Examiner	**Group Art Unit**
Deborah Clark	1633

☒ Responsive to communication(s) filed on *Apr 18, 2000*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *44-46, 50, 51, 62-64, 67-70, 74, and 78-89* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *44-46, 50, 51, 62-64, 67-70, 74, and 78-89* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Transitional After Final Practice

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on 04/18/00 has been entered.

2. Claims 44-46, 50, 51, 62-64, 67-70, 74, and 78-89 remain pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 44-46, 50, 51, 62-64, 67-70, 74, and 78-89 stand rejected under 35 USC 112, 1st paragraph for reasons of record.

The claims are summarized as follows- Claims 44-46, 50, 51, and 81-89 are directed to a method of immunizing a mammal against an immunodeficiency virus, wherein the mammal is protected from disease caused by the virus (the method claims). Claims 62-64, 67-70, 74, and

78-80 are directed to compositions comprising at least one of applicant's specifically taught constructs (the product claims). It is noted that claim 67 includes a transcription unit encoding an antigen of any other virus. It is held that the only implied or readily apparent use for the claimed compositions/plasmids is for vaccination against SIV or HIV.

Applicants present argument based upon 3 aspects of the previously set forth rejection under 35 USC 112, first paragraph, each of which will be addressed below. First, the examiner will remind applicants of other issues which were previously set forth. The method claims are not limited to SIV or HIV, but broadly encompass any immunodeficiency virus. These claims are not limited to constructs taught by applicants. The route of administration is not limited to the route demonstrated by applicants or known in the art to be effective for DNA vaccination. Claim 67 requires use of coding sequences of other antigens. DNA vaccination is not enabled for all viruses. As stated in a previous office action, only the HA of influenza has been enabled by applicants. Therefore, the claims remain to be very broad, the breadth being non-enabling.

Turning now to applicants arguments, applicants present a declaration filed under 37 CFR 1.132 by Dr. Lu. It is taken that the constructs of the previous declaration "the data declaration" are accepted as the same as that disclosed in the specification. It is further noted that the primers used in making the env fragments are the same in the Robinson declaration as that in the specification. Again it is noted that none of the method claims are limited to these constructs.

Applicants argue that the term "immunizing" refers to production of immune responses which protects, partially or totally, from the manifestations of infection. The scope of the term

includes all levels of protection. Further, it is not clear that any level of protection was realized in the data declaration. It is true that there was a rapid reduction in viral loads. Hence the viral load fell to the chronic level in 6 weeks instead of the average 12 weeks. However, CD4 counts were no different from the control group such that even an attenuation of the acute phase was obtained only if the only parameter involved was viral load. Such is not the case. The specification does not support a method of reducing viral load in the first 6 weeks following infection. Further, addition of such a limitation into the claims would raise issues under 35 USC 101 as this limited use would not rise to the level of a substantial utility. The specification implies that a therapeutic response, hence an improvement in the disease manifestation of the patient. Thus, the invention is not enabled for use.

Applicants argue that the macaque model is an appropriate model and that the reference supplied previously by applicants accurately set forth the state of the art at the time the invention was made. However, the references cited by applicants state that the model is important for study of infection. Such is not correlatable to a model to determine vaccination strategies. Further, the references cited by the examiner set forth the state of the art prior to and at the time of publication. The references are not reflective of any change in the art, but rather up to publication. Further, even if taken as demonstrative of HIV vaccine effectiveness, the data presented does not correlate to any protective effect.

Therefore, the claims stand rejected under 35 USC 112, 1st paragraph.

Conclusion

5. No claim is allowed.

6. The claims are free of the prior art of record for reasons of record.

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark whose telephone number is (703) 305-4051. The examiner can normally be reached on Mondays-Fridays from 7:10 a.m. EST to 3:40 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah Clark

DEBORAH J. CLARK
PATENT EXAMINER